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Tempus Fugit

IT HAS NOW been nearly a year since Congress passed, and the President signed into law, the 1958 Food Additives Amendment. The law became fully effective on March 5 of this year for additives first used after Jan. 1, 1958. Manufacturers of additives that had been in use before Jan. 1, 1958, were given until March 6, 1960, to complete safety tests on those additives, and secure clearance for their use from the Food and Drug Administration.

It may be that to some the day of reckoning seemed far away at the time the bill was signed, especially since the law also authorized further extension of the time, up to 12 months, where no undue risk to the public health is involved and where such extension is required. Yet, more than a third of the total time allowed—even including the maximum extension—has already passed, and the number of tolerances granted, or even requested, so far remains almost insignificant.

Out of more than 1000 additives used in American foods today, the FDA as of June 30 had received requests to clear only 26. Thirteen of the 26 petitions contained too little information to permit a decision, and were not formally filed. The manufacturers were advised that more information was necessary. Of the 13 requests filed, one was voluntarily withdrawn by the manufacturer. Only two had been acted upon by June 30, and both of those covered the same chemical, for use as a preservative of vitamins in animal feeds. Thus with more than a third of the allotted time gone, only one chemical out of more than a thousand has been cleared.

The picture is not so bleak as this would make it sound, of course. Probably several hundred of the 1000-plus additives will be designated as safe for use without further testing. FDA has already published two lists of substances it proposes to declare safe, and it is now evaluating comments of some 800 scientists throughout the country to determine which substances qualified scientists agree are safe. The first list included 188 additives used as preservatives, stabilizers, emulsifiers, and neutralizers and buffers for controlling acidity. The second list included about 180 spices and other natural seasonings and flavorings. Lists of other substances believed to be safe without further testing will be published as they can be developed.

Still, as Secretary of Health, Education, and Welfare Arthur S. Flemming emphasized at his June 30 news conference, there is a long way to go in establishing the safety of other additives by the March 1960 deadline. ". . . the clock is running," Flemming exhorted. "It would be unfortunate for both consumers and manufacturers if the March 1960 deadline compelled us even temporarily to ban useful additives which could have been cleared as safe if the requests had been submitted promptly. This could happen if requests submitted near the deadline exceeded our capacity to handle them."

Obviously, there is much more to seeking clearance than merely drawing up a petition. In many cases extensive research and toxicological tests are required, and these things take time. Yet it is often possible to speed up research through the assignment of additional personnel, or through more efficient use of those already at work. And the very least that should be done with toxicological tests involving animals is to get them started at the earliest practical date.

Efforts to speed up research and testing may call for heavier outlays of cash on a temporary basis. But in the long run, the extra costs could prove piddling in comparison with lost profits should a useful additive be forced off the market, even temporarily, by default.

It is well to remember that time is required for clearance even after the petition is submitted. Chemists, pharmacologists, medical doctors, and other scientists must review the experimental data submitted with the petition to prove that an additive is safe. FDA is building as rapidly as it can the staff and "machinery" required for such review. Scientific personnel already in the administration formed the nucleus of a scientific reviewing group. Congress appropriated funds for 60 new positions during 1959, and FDA has requested funds for another 61 positions for 1960, for food additives work.

But even if FDA gets all the funds, all the equipment, and all the personnel it wants, it will not be able to handle petitions promptly and reach decisions before the deadline, if great numbers of petitions shower upon it at the last moment. There is no time to lose.